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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/788,886 | 02/27/2004 | Andreas Reinemann | 34088/US | 4573 |

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| EXAMINER |
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MCCORKLE, MELISSA A

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| ART UNIT | PAPER NUMBER |
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3763

DATE MAILED: 09/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

CJ

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|------------------------------|--|---|--|
| Office Action Summary | Application No. 10/788,886 | Applicant(s) REINEMANN, ANDREAS | |
| | Examiner Melissa A. McCorkle | Art Unit 3763 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 February 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 27 February 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>2/27/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Priority

1. Acknowledgment is made of applicant's claim for foreign priority based on an application filed in Germany on 8/31/2001. It is noted, however, that applicant has not filed a certified copy of the Germany 101 42 637.2 application as required by 35 U.S.C. 119(b).

Information Disclosure Statement

2. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Drawings

3. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description: 9. Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the specification to add the reference character(s) in the description in compliance with 37 CFR 1.121(b) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of

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an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-3, 6, 7, 17, 18, 19, 20 and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Bokros (3,783,868). Regarding claims 1-3, Bokros teaches a implant having a surface with a surface structure improving ingrowth characteristics associated with the implant (column 12 lines 20-40), the implant comprising a non-biosorbable material (column 1 lines 10-26), and the surface structure is provided in a region of the implant, wherein after the implant is implanted the surface structure is generally adjacent to the skin (column 10 lines 60-65).

6. Regarding claims 6 and 7, Bokros teaches the surface structure generally encircling the implant (column 5 lines 61-65), and the surface structure comprising one or more grooves (column 3 lines 29-30 and column 2 lines 59-62).

7. Regarding claims 17 and 18, Bokros teaches at least two regions on surface of implant provided with a surface structure (column 12 lines 20-40) and the implant further

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comprising a holding structure with at least one passage (fig 1 & 2A, and column 12 lines 20-40).

8. In regards to claim 19, Bokros teaches the implant as a port body (fig 1).

9. Regarding claims 20 and 21, Bokros teaches a surface structure on a surface of implant wherein the surface structure improves ingrowth characteristics associated with the implant (column 12 lines 20-40) and the surface structure provided by turning a groove (column 2 line 58 – column 3 line 51). It is inherent to include the step of providing these structures for the method because the steps only include providing an apparatus.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

12. Claims 4, 5, and 8 – 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bokros. Bokros discloses applicant's basic inventive concept of an

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implant with surface structure, substantially as claimed with the exception of the specified dimensions. It would have been obvious to one of ordinary skill in the art to modify the widths and depths as claimed as a mere design choice lacking any criticality of size as being merely preferable for the intended target area (as Bokros teaches in column 4 line 55 – column 5 line 7) depending on the size of the area of the patient, where the only difference between the prior art and the claims was a recitation of relative dimensions of the claimed device and a device having the claimed relative dimensions would not perform differently than the prior art device, the claimed device was not patentably distinct from Bokros above. The parameters in claims 4, 5, and 8-16 are deemed matters of design choice well within the general skill of the ordinary artisan, obtained through routine experimentation in determining optimal results.

13. Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bokros in view of Ragheb et al (US 6,096,070). Bokros discloses applicant's basic inventive concept of an implant with surface structure, substantially as claimed with the exception of the surface structure provided by etching. Ragheb et al. shows this feature to be old in the implant art. It would have been obvious to one of ordinary skill in the art at the time of applicant's invention from the teaching of Ragheb et al. to modify the implant of Bokros by etching the surface structure for the purpose of altering the release rate of the materials or otherwise improve biocompatibility of surface of the layers.

Conclusion

14. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Bousquet, US 5,662,616 and 6,099,508 discloses a

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transcutaneous access device and transcutaneous access device, respectively; Svensson et al, US 5,098,397 discloses a percutaneous access device; Bestetti et al. US 6,270,475 discloses a port body for the administration of drugs; Hildwein et al, US 5,830,191 discloses a flexible endoscopic surgical port; and von Recum et al, US 5,219,361 discloses a soft tissue implant with micron-scale surface texture to optimize anchorage.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melissa A. McCorkle whose telephone number is (571) 272-2773. The examiner can normally be reached on Monday - Friday, 8am - 4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick Lucchesi can be reached on (571) 272-4977. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



NICHOLAS D. LUCCHESI
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Melissa A McCorkle
Examiner
Art Unit 3763

MAM